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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,929 | 12/12/2003 | Richard S. Ginn | 937.03 | 2257 |

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| EXAMINER | |
|---|---|
| YABUT, DIANE D | |
| **ART UNIT** | **PAPER NUMBER** |
| 3734 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/734,929 | GINN ET AL. | |
| | Examiner | Art Unit | |
| | Diane Yabut | 3734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25, 27-29, 31-35, and 37* is/are rejected.

7)☒ Claim(s) *26,30 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to applicant's amendment received 10 May 2007. The examiner acknowledges the amendments made to the claims and the specification.

### *Terminal Disclaimer*

The terminal disclaimer filed on 10 May 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,663,655 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-12, 14-25, 27-29, 31-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rudnick** (U.S. Patent No. **5,320,639**). Rudnick discloses a vascular plug delivery system.

Rudnick does not disclose a bioabsorbable body or plug member separate from a sealing member 18. However, Rudnick does disclose, "the plug may be provided with a more densely packed material on the outside such that complete

swelling of the plug occurs after it reaches the puncture site." It would have been obvious to one having ordinary skill in the art at the time of the invention to use a bioabsorbable material separate from the sealing member as the densely packed material disclosed by Rudnick because the densely packed material could be made from a different material, i.e. a material more dense than the sealing member. With such an interpretation of Rudnick, the sealing member is considered to be numeral 18 (figure 3) that would be disposed within this densely packed material that makes up the outer bioabsorbable body. The sealing member 18 is made of an expandable material that can expand when exposed to fluid. "The plug may also be formed from a spongy or compressed material that expands upon contact with moisture in the body." Rudnick, col. 4, lines 6-8. In other words, the plug may be considered an expandable gel foam.

Further, the sealing member comprises two configurations: a first sealed configuration and a second configuration accommodating a device through the lumen such as a guidewire or cannula. "The plug, once the cannula is withdrawn, tends to expand inwardly, thereby closing the central lumen in the plug and sealing the vessel." Id., col. 6, lines 13-15.

Numeral 212 can be considered an elongate shaft extending from the proximal end of the body. Also, depending on where the body is to be implanted, it would be obvious to one having ordinary skill in the art at the time of the invention to limit the length of the body to not more than about ten millimeters so that the body won't extend out of the wound. Further, if the wound is large, it

would have been obvious to one having ordinary skill in the art to have the body's diameter not more than about twice the length of the body.

The sealing member can be said to taper. See figure 3. The sealing member can be said to comprise a flexible material that is wedged into the tapered portion of the sealing member, as the sealing member itself is made up of flexible material. Further,as mentioned above, because the sealing member 18 is inside the lumen of the bioabsorbable body (densely packed material), it substantially seals the lumen from fluid flow therethrough.

Figure 3 also shows a connector for detachably securing the body to a delivery device.

Upon delivery of the sealing member, the plug member has a cross-section larger than a cross-section of the delivery member because the sealing member expands upon fluid contact.

Numeral 24 in figure 3 is considered to be a valve connected to the sealing member.

The distal end of numeral 212 (figure 16) acts as a location indicator, and the lumen of 212 acts as a bleed back lumen.

In regard to claim 20, "a passage" is considered synonymous with the lumen described above.

Further, the sealing member can be said to comprise a valve at its proximal end as it opens and closes to allow elongate member 12 to be inserted therethrough. Elongate member can be considered an obturator with a substantially atraumatic distal tip (figure 8). The plug member is releasable from the elongate member and is in fluid communication with the elongate member lumen (figure 8). Numeral 28 can be considered a connector that connects and deploys plug member 18 in that it releasably secures the plug member to the distal end of the elongate member.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Rudnick** (U.S. Patent No. **5,320,639**) in view of **Kamiya** (U.S. Patent No. **5,192,301**).

Rudnick does not expressly disclose that the sealing member comprises a coil of material.

Kamiya teaches a sealing member comprising a coil of material 124 (figures 12a-12b). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the sealing member in the shape of a coil, as taught by Kamiya, to Rudnick in order to recover to its original shorter length after insertion into the passage of tissue so that it may hold and close the plug tightly from both sides of the wall of the body part (col. 6, lines 27-38).

### *Allowable Subject Matter*

Claims 26, 30 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Response to Arguments*

4. Applicant's arguments with respect to claim 13 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments filed 10 May 2007 have been fully considered but they are not persuasive.

6. Applicant generally argues that Rudnick does not disclose or suggest an outer surface that is made from a completely different material than the inner plug. However, the examiner maintains that the densely packed material outer surface teaches a different property of outer material than the inner plug, and it would have been obvious to one of ordinary skill in the art to provide a bioabsorbable material on the outside since bioabsorbable outer surfaces of plugs tend to have dense, thin layers. Also, this combination would require that the outer surface of the sealing member to have a lumen, which tapers as it contains a tapered sealing member 18.

7. Applicant also argues that Rudnick does not disclose fluid communications between the plug 118 and the cannula 112. The examiner disagrees. As seen in the similar embodiment in Figure 2, the elongate member

12 and plug 18 are coaxial and therefore are considered to be in fluid communication with one another.

8. Lastly the applicant argues that the valve, or hub assembly, 24 is not in the plug member lumen as necessitated by Claim 21. As maintained above, the outer surface makes up the outer bioabsorbable body and the plug 18 makes up the sealing member, which is disposed inside the lumen of the bioabsorbable body. Claim 24 necessitates that the sealing member comprises a valve, and Rudnick's sealing member 18 comprises valve 24.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER